Module 9d: Other Compliance/Noncompliance – Other Consumer Protection

Goal To provide instructions to in-plant inspection personnel for determining an establishment's compliance with HACCP, SSOP, Salmonella, and other nonrelated HACCP and pathogen requirements.

Objective After completing this module, participants will be able to:

1. Define what "Other Compliance/Noncompliance" means related to Other consumer protection procedures.

2. Be able to apply the Other consumer protection procedures.

3. Be able to document findings and take enforcement actions when Other consumer protection procedures are not met.

At this time regulatory requirements for other consumer protection activities such as misbranding/mislabeling or economic adulteration have not changed. The Deficiency Classification Guide will no longer be used in establishments subject to the Pathogen Reduction/HACCP regulations. The Noncompliance Determination Guide covers all areas of FSIS regulatory responsibility. FSIS will use trend indicators in determining whether to take additional regulatory or administrative action based on establishment performance.

Industry must prevent contamination and adulteration and comply with FSIS regulations. When contamination or adulteration occurs, the establishment management has the responsibility to bring the establishment into compliance by controlling the immediate situation and preventing recurrence of the problem. Actions that do not accomplish both are inadequate. In other words, adulterated or misbranded product must not be produced, but if contamination or adulteration occurs, corrective actions must be taken to prevent the product from being distributed and preventive measures taken to prevent recurrence.

FSIS will continue to have responsibility of ensuring that adulterated product does not enter commerce, even though this type of adulteration is not a safety hazard. For example, if product identified as “Bologna, made with beef and chicken” is being labeled as “Beef Bologna”, inspection personnel would initiate official control actions, document the noncompliance on an NR, and mark the “Misbranding” trend indicator on the Process Schedule and the Noncompliance Record. In other situations, official control actions might not be necessary, but the noncompliance would still be recorded on an NR and given to management as notification of the failure to comply with regulatory requirements. For example, if unused equipment and supplies were stored on the ground outside the plant and a mouse is seen running under the equipment, the “outside premises” trend indicator would be marked on the PS and NR. The noncompliance would be documented on the NR and given to plant management as notification of failure to meet regulatory requirements. The establishment is responsible for bringing itself into compliance with regulatory requirements. The establishment actions should address proper product disposition and measures to prevent recurrence. Documentation of recurring or repeated noncompliance with regulatory requirements will be used as a basis for further FSIS actions.

1. What are the changes to the regulatory requirements for the other consumer protection activities such as misbranding/mislabeling or economic adulteration?

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   _____
   _____
   _____

2. How will FSIS determine whether to take additional regulatory or administrative action for other consumer protection issues?

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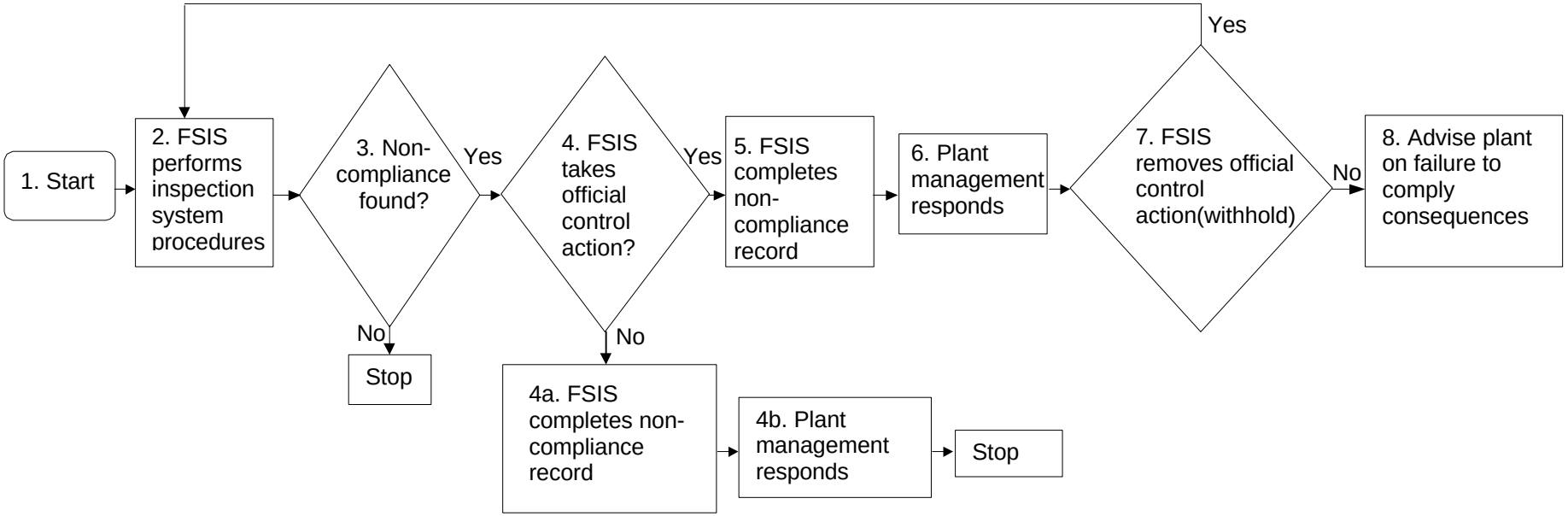
Attachment 1

Regulatory Process For **Other** Consumer Protection Activities



GUIDELINES FOR PROCEDURES IN ACTIVITIES 04, ECONOMIC/WHOLESOMENESS, AND 06, OTHER REQUIREMENTS

Activity 04, Economic/Wholesomeness

- **Element 04A**

This element is used to verify product requirements traditionally recognized as prevention/control of economic adulteration. There are four procedures within this element.

Procedure **04A01** is used to verify regulatory requirements for products subject to yield, shrink, and/or green weight restrictions.

Procedure **04A02** is used to verify regulatory requirements for declaration of added substances.

Procedure **04A03** is used to verify economic requirements for the range of mechanically manufactured meat and poultry products not produced from whole muscle, such as mechanically separated meat, mechanically deboned poultry, low temperature rendered products, etc. This procedure is also used to record noncompliance with the removal of poultry kidneys, sex glands, and lung requirements.

Note: FSIS sampling for mechanically separated poultry bone content is recorded under procedure 05B01.

Procedure **04A04** is used to verify regulatory requirements for amounts of batter and/or breading on meat and poultry products.

Note: In all these instances, food safety and public health requirements are considered part of HACCP verification and not recorded under these procedures. For example, the temperature to which battered and breaded products are cooked is verified using the appropriate HACCP (03) Element. The requirement that batter not exceed 30% of the finished product is verified using 04A04.

- Element 04B

This element has four procedures that encompass the labeling and standards requirements for meat and poultry and meat and poultry food products.

Procedure **04B01** is used to verify regulatory requirements for product standards. Examples of such requirements are the amount of meat in soups, the amount of meat in chili or hash, the percent poultry in specific dishes such as (kind) dumplings, (kind) salad, (kind) tetrazinni, etc.

Procedure **04B02** is used to verify labeling requirements ~~for~~ of meat and poultry products for the Child Nutrition programs, graded products, those that state a declared count, or bear a vignette.

Procedure **04B03** is used to verify net weight requirements.

Procedure **04B04,** general labeling, is used to verify general labeling regulatory requirements. It covers all labeling requirements. But it **should not** be used for the specific requirements covered by the procedures previously discussed. It is used to document compliance/noncompliance with restricted ingredient requirements when these are not food safety related (for example binders, extenders, flavorings, coloring agents, etc.). In these cases, noncompliance occurs only when the order of predominance on the label is affected, or the ingredient is not added in an amount permissible by regulation.

Use this procedure to document noncompliance when undeclared species determinations are made.

This procedure should also be used to record the result of determinations regarding compliance and noncompliance with requirements for letters of guarantee for packaging materials, food ingredients, etc. These regulations are presently undergoing revision.

Note: Until changes are made, **nonfood ingredients** such as cleaning chemicals should be addressed using procedure 06D01. The labeling and use of pesticides and rodenticides are covered under procedure 06G.

- Element 04C

Procedure **04C01** covers finished product standards, boneless meat reinspection, pork skins for popping, and AQLs. It is used to document compliance/noncompliance with ingesta that exceeds FPS, and inflammatory processes that are diseases or conditions that don't have human health implications. This procedure is used to document compliance/noncompliance of off condition product. Off condition product, that which exhibits spoilage conditions, is not a public health issue. Spoilage organisms are not known to be pathogenic to humans. Appropriate enforcement action should be taken to ensure that unwholesome product does not enter commerce. Poultry salvage noncompliance, air sac, inflammatory processes, and turkey osteomyelitis should be documented using this procedure.

Activity 06, Other Requirements

The 06 Activity consists of six elements. The procedures in this Activity are designed for verifying **other** regulatory requirements.

Note: Regulatory requirements that fall under the provisions of the Sanitation Standard Operating Procedures (SSOPs) and/or HACCP are not included in these elements.

- **Element 06A**

Procedure **06A01** is used to verify export requirements. This procedure **is not** used to verify that the product is produced in a sanitary environment and is not adulterated, but rather that product is appropriately staged, marked, and that the certification requirements of foreign countries and FSIS are met.

- **Element 06B**

Procedure **06B01** is used to verify regulatory requirements in establishments producing custom exemption and retail products. Noncompliance will be product related. Any noncompliance with facility or sanitation requirements will be recorded under the appropriate procedure as in any other establishment.

- **Element 06D**

There are three procedures within this element.

The first procedure, **06D01**, is used to verify regulatory requirements for facilities and equipment. These requirements are for the most part structural and mechanical. This procedure also is used to record compliance/noncompliance with regulatory requirements concerning condensation. Direct product contamination or adulteration is covered using the SSOP procedure for operational sanitation.

Procedure **06D02** is used to verify structural, mechanical, and other regulatory requirements designed to ensure that FSIS inspection personnel can conduct inspection.

Procedure **06D03** is used to verify regulatory requirements for condemned and inedible materials. The focus of this procedure is on requirements for proper denaturing, marking of inedible containers, and separation from edible product. When food safety or sanitation noncompliance is involved, the appropriate SSOP or HACCP procedure should be used.

- **Element 06E**

Procedure **06E01** is used to verify regulatory requirements regarding sewage and waste disposal. This element contains a single procedure and is intended to reflect structural and mechanical requirements. This procedure **is not** intended for use when product is adulterated as a result of noncompliance.

- **Element 06F**

There are two procedures within this element.

The first procedure, **06F01**, is used to verify that appropriate water certificates are on file and current.

Procedure **06F02** is used to verify “other” regulatory requirements involving water use and reuse.

- **Element 06G**

Procedure **06G01** is used to verify regulatory requirements for the control of pests and vermin. This procedure **is not** used in cases of direct product contamination and adulteration.

Noncompliance Determination for Activities 04 and 06

When noncompliance is determined in any of these Activities, elements, or procedures the instructions in FSIS Directive 5400.5 should be followed. Noncompliance is documented on a Noncompliance Record and the appropriate procedure code is recorded on the NR, and if appropriate, on a blank procedure schedule, FSIS Form 5400-3. If inspection personnel are performing a scheduled or unscheduled procedure in Activity 04 or 06 and determine that noncompliance results in economically adulterated product being produced, the appropriate control action should be taken on the product and noncompliance recorded.

Note: When performing ISP procedures for HACCP-based inspection compliance/noncompliance determinations are made based on the conditions that exist in the plant and not on the probability that something "may occur". The plant is responsible for meeting these regulatory requirements and ensuring that adulterated/misbranded product is not produced and shipped.